

Appl. No. 10/032,962
Resp AF dated January 10, 2006
Reply to Final Office Action of November 14, 2005

REMARKS

Applicant has carefully reviewed the Final Office Action mailed November 14, 2005, prior to preparing this response. Currently, claims 1-5 and 7-22 are pending in the application, wherein claims 1-5, 8, 11-14 and 16 have been rejected and claims 7, 9, 10, 15 and 17-22 have been withdrawn from consideration consequent an Examiner-induced restriction requirement. Favorable consideration of the following remarks in view of the pending claims is respectfully requested.

Claims 1-5, 8, 11-14 and 16 stand rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Shoup et al., U.S. Patent No. 5,591,129, (hereinafter Shoup). Applicant respectfully traverses this rejection.

Applicant respectfully asserts that the Examiner erroneously maintains an unreasonable interpretation of a balloon waist as that term is described in the current application and recited in the claims. In the Office Action the Examiner asserts, "the entire section between these two areas 19 and 29 may fairly be considered a waist. In any event, a waist, by definition, is an area of reduced diameter." This interpretation, indeed, is contrary to the definition attributed to the term in the current application, the express teachings of Shoup, and the ordinary and customary meaning of the term accepted by those of ordinary skill in the art. Indeed, the Examiner is under an obligation to give the claim term a reasonable interpretation consistent with the interpretation that those skilled in the art would reach. See M.P.E.P. §2111, citing *In re Cortright*, 165 F.3d 1353, 49 USPQ2d 1464 (Fed. Cir. 1999).

As described in the current application (see Specification, page 4, lines 1-17, for example), a balloon typically includes an expandable portion intermediate a proximal balloon waist and a distal balloon waist. The balloon waist (e.g., proximal waist and/or distal waist) provides an interface to sealingly connect the balloon to an underlying tubular member extending through and in contact with the balloon waist.

This interpretation is consistent with the express teachings of Shoup. Shoup defines the balloon envelope 16, and thus the extents of the balloon, as that portion extending from the proximal waist 18 to the distal waist 19. See Shoup, column 4, line 66 through column 5, line 1 and column 5, lines 7-9. The distal waist 19 is the portion of the balloon envelope 16 attached to the perfusion lumen 17. Shoup further describes a balloon assembly tip 25 extending distally

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from the balloon envelope 16 at the distal end of the perfusion lumen 17. See Shoup, column 5, lines 33-36. As identified in claim 1, as well as at column 2, lines 57-64, an improvement of the perfusion balloon catheter taught in Shoup over the prior art is the presence of a projecting tip 25 extending distally from the balloon envelope 16, and thus from the distal end of the distal waist 19. Even though the projecting tip 25 is integrally formed with the balloon envelope 16 in order to negate the effect on trackability of stiffness transitions within the assembly, the projecting tip 25 is a distinct element of the assembly disclosed in Shoup separate from the balloon envelope 16. See column 2, lines 57-64. Therefore, the portion extending distal of the distal waist 19 is not considered to be a portion of the distal waist 19, but instead is a tip 25 integrally formed of the material which forms the balloon envelope 16. Thus, Shoup expressly discredits the notion that everything distal of element 19 is considered a balloon waist. It is the projecting tip 25, not the distal waist 19 that includes the orifices 26, 27.

Moreover, one of ordinary skill in the art would conclude that a balloon waist is the portion of balloon material sealingly secured to an underlying tubular member. It follows that the portion of a balloon sealingly connected to an underlying tubular member may be considered a balloon waist, but not every reduced diameter portion of a balloon may be considered a balloon waist.

Furthermore, Shoup teaches that the projecting tip 25, not the distal waist 19, includes the orifices 26, 27. See Shoup, column 5, lines 35-50. The orifices 26, 27 are unobstructed by other portions of the assembly and in are fluid communication with the interior of the projecting tip 25 and the perfusion lumen 17. Thus, the orifices 26, 27 may facilitate the egress of fluid through the perfusion lumen 17. If the portion of the assembly including the orifices 26, 27 is subjected to thermal reformation as proposed by the Examiner, then the orifices 26, 27 would become obstructed and the perfusion balloon catheter taught by Shoup would cease to function as intended. The inner surface of the portion of the material having the orifices 26, 27 is not in contact with or secured to another object of the assembly. The orifices 26, 27 are intended to remain unobstructed and open from the inside of the balloon such that fluid may egress through the orifices 26, 27. Therefore, not only is there no motivation to secure the portion including the orifices 26, 27 to a tubular member, but such a modification would render the proposed design unsuited for its intended purpose.

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For at least the reasons stated above, Shoup fails to anticipate, or render obvious, the invention claimed in claim 1. Applicant submits that claim 11, is allowable for similar reasons. As each of claims 2-5, 8, 12-14 and 16 depend directly or indirectly from one of claims 1 and 11, and contain additional elements, Applicant submits that these claims are additionally in condition for allowance.

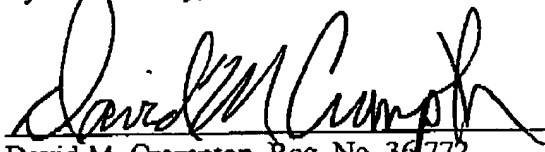
Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By his Attorney,

Date: 1/10/06


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